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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): P-5856

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

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Signature _____

Typed or printed name _____

Application Number	Filed
10/530,817	April 8, 2005

First Named Inventor: Thomas A. Alheidt

Art Unit	Examiner
3767	Schell, Laura C.

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☑ attorney or agent of record.
Registration number 32135.

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

/Donna R. Fugit, Reg. #32135/
Signature

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Typed or printed name

732 815-0404
Telephone number

February 22, 2011
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

☑ *Total of 1 forms are submitted.

PRE-APPEAL BRIEF REQUEST FOR REVIEW

This Request is submitted in view of the Examiner's omission of one or more essential elements needed for a *prima facie* rejection. As the response to the Final Rejection mailed November 22, 2010, is due by February 22, 2011, this paper and the accompanying Notice of Appeal are timely filed.

SUMMARY OF REJECTIONS

Claims 4-6 and 23 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Laffy et al. (US 5373971). According to the Examiner, Laffy discloses a syringe capable of being used as an IV flush syringe which includes an inside surface having a contact area at the distal end of the barrel which is roughened. The "roughened" portion is alleged to be the notches or teeth formed on the inside surface of the barrel which will dig into the plunger stopper and prevent it from moving rearwardly once it has been advanced. *See page 2, line 16 – page 3, line 3 of the Final Office Action with reference to feature 10 of Figs. 10 and 11.* It is also alleged that this contact area has a higher coefficient of friction than the inside surface outside the contact area for frictionally engaging the stopper. *See page 3, lines 11-2 of the Final Office Action.*

Claim 4 is directed to an IV flush syringe assembly and is the only independent claim pending. Claim 4 recites that "…said contact area has a higher coefficient of friction than said inside surface outside of said contact area for frictionally engaging said stopper when said stopper is in contact with said distal wall of said barrel for frictionally holding said stopper in a partially deflected position…"

OMISSION OF ELEMENTS NEEDED FOR *PRIMA FACIE* REJECTION

The claim limitations of a contact area having a higher coefficient of friction than the inside surface of the barrel outside the contact area for frictionally engaging said stopper and for frictionally holding said stopper in a partially deflected position are not met by the notches or teeth which dig into the plunger stopper of Laffy.

The Examiner has characterized the notches or teeth of Laffy as providing frictional engagement of the stopper; however, this characterization is technically incorrect. The term "friction" refers to the resistance encountered when one body is moved in contact with another or to the effort expended in moving one object over another with pressure. Friction describes interactions between two surfaces which resist sliding over each other.

Laffey describes the notches or teeth shown in Fig. 10 as being "oriented in the direction of the outlet orifice, so as to oppose any movement of the piston 4 in the opposite direction and block it in the position attained." *Col. 8, ln. 66-col. 9, ln. 3 of Laffy.* The description of the notches or teeth being "oriented" in a distal direction teaches that they act as barbs which allow the piston to slide over them in the distal direction but then dig into the piston to prevent subsequent rearward motion. The description of the notches or teeth as "blocking" the piston in the position attained teaches that they create a physical barrier to prevent rearward movement. That is, the notches or teeth project into the barrel from its inside surface to create a section of the barrel which is narrower than the width of the plunger stopper. This causes the notches or teeth to dig into the plunger and prevent its rearward movement. Both of these teachings confirm that Laffy's notches and teeth function by physically blocking piston movement.

Physically blocking the piston stopper by narrowing a portion of the barrel with notches or teeth, as in Laffy, does not teach or suggest frictionally holding the stopper in a deflected position nor does it rely on a higher coefficient of friction in the contact area to prevent stopper movement as required by claim 4. Once captured on the notches or teeth, the plunger stopper is not held against rearward movement by its interaction with the surface of the barrel (i.e., which defines friction) – it is held against rearward movement by its interaction with the notches or teeth (i.e., physical blocking of rearward movement).

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). In addition, for an anticipation rejection to be proper, the reference must clearly and unequivocally disclose the claimed subject matter or direct those skilled in the art to the claimed subject matter without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference. *See In re Arkley*, 455 F.2d 586, 587 (CCPA 1972); *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1334 (Fed. Cir. 2008). The claim limitations relating to a contact area with a higher coefficient of friction than other portions of the syringe barrel, frictionally engaging the stopper and frictionally holding the stopper are not met by Laffy. Further, Laffy does not suggest friction or any other alternative to physical

blocking of rearward movement of the plunger stopper using notches or teeth. Laffy therefore does not anticipate independent claim 4 or claims 5, 6 and 23 dependent therefrom.

Dependent claims 18-21 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Laffy et al. (US 5373971) in view of Lynn (US 5522804). Lynn is relied upon for disclosure of a flush syringe with a tip cap and flushing solution in the chamber of the syringe, wherein the flushing solution is saline. Lynn is further relied upon for disclosure of a needle assembly attached to the end of the syringe. *See page 5, lines 10-18 of the Final Office Action.* It is allegedly obvious to modify Laffy with these features as taught by Lynn. Dependent claim 22 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Laffy et al (US 5373971) in view of Greenwood (US 5120314). Greenwood is relied upon for disclosure of a stopper made from rubber. It is allegedly obvious to modify Laffy with the rubber stopper of Greenwood. *See page 6, lines 2-6 of the Final Office Action.*

None of the disclosures referenced in Lynn or Greenwood overcome the failure of Laffy to disclose a contact area with a higher coefficient of friction to prevent stopper movement, frictionally engaging the stopper or frictionally holding the stopper in a deflected position. *Prima facie* obviousness has therefore not been established with respect to claims 18-22, as an essential element of the independent claim from which they depend is omitted.

CONCLUSION

For the foregoing reasons, Applicants submit that anticipation and *prima facie* obviousness have not been established for claims 4-6 and 18-23 of the present patent application, and that the claims are patentable over the cited prior art. It is believed that no fees are due in connection with this submission, however, if fees are found to be due, the Commissioner is authorized to charge Deposit Account No. 50-3329.

Respectfully submitted,

Dated: February 22, 2011

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